

UTERINE FIBROID EMBOLIZATION (UFE)

These guidelines are jointly produced by the Society of Obstetricians and Gynaecologists of Canada (SOGC), the Canadian Association of Radiologists (CAR), and the Canadian Interventional Radiology Association (CIRA).

This document has also been reviewed by the Clinical Practice Gynaecology Committee and approved by the Executive and Council of the Society of Obstetricians and Gynaecologists of Canada.

We recommend that these guidelines be reviewed and updated on a regular basis by a joint committee of the SOGC, CAR, and CIRA. They should be made widely available to physicians and patients contemplating uterine fibroid embolization.

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Abstract

Objective: To help direct the organized and effective implementation of uterine fibroid embolization into clinical practice in Canada.

Options: This document is restricted to the management of uterine fibroid embolization as performed by the radiologists utilizing a trans-femoral artery approach with arteriography followed by vessel embolization.

Outcomes: Uterine fibroid embolization has been evaluated in terms of patient satisfaction, risks of complications, risks in subsequent pregnancy and rate of hysterectomy within a few months of the procedure. As the procedure is relatively new, data on long-term outcomes are not available.

Evidence: Published opinions of experts, supplemented by evidence from clinical trials where appropriate.

Values: The quality of the evidence is rated using the criteria described by the Canadian Task Force on the Periodic Health Examination.

Benefits, Harms, and Costs: For women presenting with symptomatic uterine fibroids who are candidates for UFE, there is often a benefit to avoiding an abdominal surgery. The

risks of the UFE procedure, possible complications, and short- and long-term prognosis must be measured on an individual basis against the well-studied surgical alternatives. Patient preference is an important component of this evaluation. The non-material costs of ongoing symptoms from the fibroids are difficult to measure and use comparatively against the cost of hospitalization and treatment. In evaluating costs of UFE, the calculations should take into consideration the cost of managing occasional complications including subsequent hysterectomy. The cost of myomectomy or hysterectomy will vary largely depending on technique used and length of hospital stay.

Recommendations:

1. Women considering treatment of fibroids should be counselled that while the early results of uterine artery embolization are encouraging, no long-term data exist. (II-2-B)
2. UFE should only be considered for women with symptomatic or problematic fibroids who might otherwise be advised to have surgical treatment. (III-A)
3. UFE as a treatment for fibroids in patients wishing to preserve their fertility should be undertaken with full disclosure to the patient about the limitations of such a procedure and the lack of existing data regarding future fertility and pregnancy outcomes. (III-C)
4. UFE is contraindicated in women who have evidence of current genitourinary infection and/or malignancy. (II-2-B)
5. Women who choose UFE as an alternative to hysterectomy should be counselled regarding the risk of major complications

Key Words

Uterine artery embolization, uterine myomas, uterine fibroids, leiomyoma, hysterectomy, myomectomy, interventional radiology, menometrorrhagia, dysfunctional uterine bleeding

These guidelines reflect emerging clinical and scientific advances as of the date issued and are subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed. Local institutions can dictate amendments to these opinions. They should be well documented if modified at the local level. None of the contents may be reproduced in any form without prior written permission of SOGC.

of UFE where hysterectomy may be urgently required and potentially lifesaving. In view of this small but important risk, UFE is relatively contraindicated in women who are unwilling to have a hysterectomy under any circumstances. (III-C)

6. Genitourinary infection is the predominant cause of serious morbidity and mortality. Further research on the utility of prophylactic antibiotic therapy and the value of pretreatment screening for infection is needed. (II-2-B)
7. A gynaecologist who is familiar with UFE should evaluate all patients considered for UFE before the procedure is booked and a consensus on the suitability of the procedure achieved between the gynaecologist and radiologist. (III-C)
8. Only radiologists with specialized embolization experience and techniques should perform UFE. (III-C)
9. The particular responsibilities of both gynaecologist and radiologist should be established prior to treatment and be set out in a relevant hospital protocol. A particular physician must be responsible for the patient at all times. (III-C)
10. A Canadian national registry of numbers, indications, outcomes, complications, and successful pregnancies associated with UFE should be created and jointly administered and funded by the SOGC, CAR, and CIRA. (III-C)

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INTRODUCTION

Leiomyomata are the most common tumours in women. The Society of Obstetricians and Gynaecologist of Canada published guidelines on the management of fibroids in 2003, which reviewed the available evidence for diagnosis and management both medical and surgical.¹

Uterine artery embolization has been used during the last 2 decades in a variety of clinical settings including postpartum hemorrhage, bleeding after Caesarean section, and bleeding following gynaecological surgery.² The technique was extended in later years to include the management of arterial venous

malformations of the genital tract as well as gestational trophoblastic disease. Ravina first used arterial embolization to treat fibroids in 1991, publishing his first series in 1995.³ Since that time, many thousands of uterine artery embolizations have been performed worldwide and there is increasing public awareness of the availability of this new technology. The Royal College of Radiologists and the Royal College of Obstetricians and Gynaecologists in the United Kingdom recognized the importance of interdisciplinary collaboration and published a joint guideline for the management of women who choose uterine fibroid embolization (UFE).⁴ As the procedure increases in popularity and with the apparent efficacy of this technique, the Society of Obstetricians and Gynaecologists of Canada (SOGC), the Canadian Association of Radiologists (CAR), and the Canadian Interventional Radiology Association (CIRA) formed committees to prepare this guideline within a Canadian perspective.

Ischemia of uterine fibroids may be achieved by a variety of techniques. Laparoscopic uterine artery occlusion has been shown to yield equivalent results to UFE in the short term utilizing bipolar coagulation^{5,6} or clips.⁷ Furthermore, a procedure of temporary bilateral uterine occlusion performed with intravaginal, "incisionless" application of a paracervical clamp with integrated audible Doppler ultrasound to treat uterine fibroids has been reported.⁸ Discussion of the alternative treatments including medical and surgical options for uterine fibroids is presented elsewhere and will not be covered in this document.¹

The quality of evidence reported in these guidelines has been described using the Evaluation of Evidence criteria outlined in the Report of the Canadian Task Force on the Periodic Health Exam (Table).⁹

ADVANTAGES AND RISKS OF UFE

UFE is emerging as an effective alternative to hysterectomy and

Table.

Quality of Evidence Assessment ⁹	Classification of Recommendations ⁹
<p>The quality of evidence reported in these guidelines has been described using the Evaluation of Evidence criteria outlined in the Report of the Canadian Task Force on the Periodic Health Exam.</p> <p>I: Evidence obtained from at least one properly randomized controlled trial.</p> <p>II-1: Evidence from well-designed controlled trials without randomization.</p> <p>II-2: Evidence from well-designed cohort (prospective or retrospective) or case-control studies, preferably from more than one center or research group.</p> <p>II-3: Evidence obtained from comparisons between times or places with or without intervention. Dramatic results in uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in this category.</p> <p>III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.</p>	<p>Recommendations included in these guidelines have been adapted from the ranking method described in the Classification of Recommendations found in the Report of the Canadian Task Force on the Periodic Health Exam.</p> <p>A. There is good evidence to support the recommendation that the condition be specifically considered in a periodic health examination.</p> <p>B. There is fair evidence to support the recommendation that the condition be specifically considered in a periodic health examination.</p> <p>C. There is poor evidence regarding the inclusion or exclusion of the condition in a periodic health examination, but recommendations may be made on other grounds.</p> <p>D. There is fair evidence to support the recommendation that the condition not be considered in a periodic health examination.</p> <p>E. There is good evidence to support the recommendation that the condition be excluded from consideration in a periodic health examination.</p>

myomectomy for symptomatic fibroids. Although early results are encouraging, there are no long-term data available. The initial report of UFE was published in 1995 by Ravina *et al.*³ The same group subsequently reported excellent results with a larger series of 88 patients who were followed up to 5 years.¹⁰ Mean fibroid volume reduction (largely ultrasound assessed) was reported at 69% with procedural success reported at 89% (although their definition of “success” was not stated). Nine patients (10%) in this series underwent hysterectomy; 8 for pain and 1 for bleeding associated with a sub-mucous fibroid. Since then it is estimated that 40 000 women have been treated worldwide. Numerous case series have been published.

Pron *et al.*¹¹ reported on the Ontario Uterine Fibroid Embolization Trial, which enrolled 555 women. The median follow-up was 8.9 months. Menorrhagia improved in 83% of women following the procedure, dysmenorrhea improved in 77%, and urinary frequency improved in 86% of women. The mean fibroid volume reduction for the dominant fibroid was 33% at 3 months. Amenorrhea occurred in 8% of women (3% of women under 40 and 41% of women over age 50). The complication-related hysterectomy rate in the Ontario UFE Trial was 1.5% within 3 months of the embolization.¹² Of the 8 procedures, 2 were for infection, 4 for persistent post-embolization pain, 1 for a 10 cm prolapsed leiomyoma, and 1 for persistent vaginal bleeding.

Walker and Pelage¹³ reported on 400 patients with an average follow-up of 16.7 months. Menstrual bleeding improved in 84% and dysmenorrhea improved in 79%. Seven percent of women experienced amenorrhea and 3.5% of women expelled fibroids per the vagina. Three patients (1%) developed endometritis requiring hysterectomy. Twenty-six women (6%) had clinical failure, meaning that their symptoms did not resolve.

The first quality-of-life assessment was reported by Worthington-Kirsch in 1998.¹⁴ This series has recently been upgraded and is now the largest in the literature, with 305 patients entered.¹⁵ Follow-up was restricted to 3 months. There were 6 hysterectomies in the series but none for infectious complications. Average fibroid volume reduction was not stated; but the success rate—defined as improvement in menorrhagia, pain, and pressure, as well as overall patient satisfaction—was reported as 92%. Thirteen fibroid expulsions were reported in this series, all without complication. Quality-of-life was also addressed by Spies *et al.*¹⁶ Health-related quality of life was improved in all 50 cases at 3 months. Mean change scores were statistically significant for all domains up to 3 months ($P < 0.01$) and up to 6 months ($P < 0.05$), other than backache ($P = 0.12$).

Spies *et al.*¹⁷ reported on 200 women with a mean follow-up of 21 months. At 1 year post-UFE, menorrhagia was improved in 90% of women and bulk symptoms improved in 91%. Complications after 400 consecutive UFE cases were reported by this group. Peri-procedural complications (defined

as complication within 30 days of the procedure) occurred in 34 patients (8.5%). Ten women (2.5%) passed fibroids. Two women developed endometritis. One woman had a pulmonary embolus 3 days after the procedure. Another patient developed bilateral iliac artery thrombosis. Two women had hysterectomies—1 for a uterine infection 10 weeks after embolization, and 1 required hysteroscopic myomectomy for incomplete expulsion of a fibroid with associated menorrhagia.

Having reviewed these published series, it appears that menorrhagia and bulk or pressure symptoms are alleviated in 80 to 90% of patients by 1 year. Mean fibroid volume reduction at 1 year range from 50 to 60%. Hysterectomy or myomectomy for complications occurred in 1% of patients. Readmission for infections occurred in 1%. Infections can occur several months after the procedure. Delayed post-procedural pain should raise suspicion of uterine infarction. This complication can lead to infection and always results in hysterectomy in the women studied.

At least 5 deaths have been reported after UFE. The first reported case involved septic shock secondary to *Escherichia coli* in the United Kingdom.¹⁸ The patient was thought to have an asymptomatic urinary tract infection at UFE. In the second case, a 60-year old Italian woman with known breast cancer underwent UFE for fibroid disease. After several days of inpatient treatment she developed a pulmonary embolus and died.¹⁹ Another death from septic shock after embolization was reported by de Blok *et al.* in the Netherlands.²⁰ At autopsy, there was extensive ischemic necrosis of the uterus. Cultures revealed group A streptococcus.²⁰ In the United States, 2 deaths following UFE were reported by Robert Worthington-Kirsch at the 31st Annual Meeting of the American Association of the Gynecologic Laparoscopists held November 20 to 24, 2002 in Miami Beach, Florida (personal communication with Worthington-Kirsch, Society of Interventional Radiology UFE Task Force member).

RECOMMENDATIONS

1. **Women considering treatment of fibroids should be counselled that while the early results of uterine artery embolization are encouraging, no long-term data exist. (II-2-B)**
2. **UFE should only be considered for women with symptomatic or problematic fibroids who might otherwise be advised to have surgical treatment. (III-A)**

PATIENT ASSESSMENT

While safety and efficacy of the technique are being established, we believe that UFE should only be recommended to women with symptomatic fibroids who might otherwise be advised to have surgical treatment. Symptoms might include menorrhagia, dysmenorrhoea, dyspareunia, and other pressure effects of

the fibroid on the urinary or gastrointestinal tract. Patients should be informed of the limitations of UFE. Women who are infertile (or who may wish to become pregnant subsequently) present particular problems. Women who have medical conditions contraindicating surgery, who are unwilling to receive a blood transfusion (e.g., Jehovah's Witnesses), or who have had previous unsuccessful fibroid surgery may find UFE an acceptable method of treatment. Patients must however recognize that complications of the procedure may require hysterectomy.

INDICATIONS FOR UFE

Accurate pre-treatment diagnosis is essential and should be made by the referring gynaecologist. Any patient with demonstrated fibroids where the potential for symptomatic relief overrides the potential for complications and where there is no contraindication, would be a candidate for UFE. Appropriate steps should be taken to ensure that presenting complaints relate to fibroids and are not due to unrelated pathology. The uterine cavity should be carefully evaluated and abnormal uterine bleeding should be appropriately investigated prior to contemplating UFE. If the fibroids are sub-mucous, consideration should be given to hysteroscopic management.^{1,21}

Magnetic resonance imaging (MRI) is superior to ultrasound (US) in delineating fibroids and is more likely to permit recognition of adenomyosis if present, however MRI is not readily accessible across the country. The value of UFE in adenomyosis is unproven but may be indicated when fibroids and adenomyosis coexist. It should be noted that UFE is almost always performed without a tissue diagnosis of the fibroids to be treated. The radiologist undertaking the procedure should watch for atypical imaging findings that are not characteristic of fibroids. There have been several cases of presumed fibroids, which did not respond to UFE and later proved to be sarcomas.²²⁻²⁵

UFE will not be the preferred method of treatment in all instances, and evaluation by both gynaecologist and radiologist will be necessary to determine appropriate selection.

At present, there are insufficient data to advocate UFE as a means of preserving fertility in those who require relief from symptomatic fibroids; and, likewise, there is not sufficient evidence yet to recommend UFE as a means of treating suspected fibroid-induced infertility.

CONTRAINDICATIONS

While some fibroids (large or pedunculated or very numerous) may not respond as well to UFE, there is insufficient evidence to prescribe UFE based solely on size or number of fibroids. The decision to proceed with UFE should be individualized in the context of predicted risks and benefits as compared with other available modalities of treatment. Absolute contraindications to UFE include active genitourinary infection and/or malignancy, reduced immune status, severe vascular disease limiting access, radiographic contrast media allergy, and impaired renal

function which contrast medium may worsen. The relative contraindications related to fibroid morphology (or presence of adenomyosis) need to be weighed against the anticipated benefit of UFE and the relative risks of surgery. Sub-mucosal and pedunculated fibroids may be considered relative contraindications as are previous internal iliac or uterine artery occlusion or recent GnRH analogue administration.

INFERTILE PATIENTS AND THOSE CONTEMPLATING A SUBSEQUENT PREGNANCY

Reports of successful term pregnancies following UFE for a variety of indications have been summarized by Goldberg *et al.*²⁶ who reported 34 pregnancies after UFE. The spontaneous abortion rate was 32%, the postpartum hemorrhage rate was 9%, the premature delivery rate was 22%, the malpresentation rate was 22%, and there was a 65% rate of Caesarean delivery.

In the Ontario UFE multicentre trial,¹² 555 women with symptomatic fibroids were embolized from June 1998 to November 2000; of these women, 164 (30%) desired future fertility. Seventeen women achieved pregnancy, 2 of them twice and 18 of 19 pregnancies were achieved spontaneously. The pregnancy outcome following UFE were 14 live births (8 term, 6 preterm), 4 spontaneous abortions (15.8%), and 1 therapeutic abortion. Eight were Caesarean deliveries, 2 for placenta previa. There were 2 placenta accretas and 1 membranous placenta. In view of this high risk of placental complications, it may be prudent to follow pregnancies after UFE in a special pregnancy clinic with access to ultrasound with capabilities for early placental studies looking for placenta accreta, which may result from implantation over an area denuded of endometrium.²⁷

Patients expressing interest in embolization as a means of restoring fertility must be made aware of the potential complications of the procedure, and cautioned that restoration of fertility is not yet a recognized indication for the procedure. In addition, the potential for adverse effects to a subsequent pregnancy have not yet been determined.²⁷

Notwithstanding these limitations, the patient, gynaecologist, and radiologist must evaluate the risks and benefits of such a procedure on an individual basis. Women who elect to undergo UFE for the more accepted gynaecological indications should be told that the effects of the procedure on pregnancy and delivery are uncertain as there are insufficient data on this subject. Infertility and recurrent miscarriage should not currently be regarded as a usual indication for UFE until a controlled clinical trial with appropriate approval by an ethics committee has determined the safety and efficacy. It is recommended that the above advice be included in the written information given to the patient before initial meetings with the radiologist and/or gynaecologist and that a written consent form should be devised that clearly records that the patient understands these risks. Pregnancies will continue to occur following fibroid embolization. It is very important to collect, evaluate,

and disseminate information on these pregnancies.

Myomectomy remains an acceptable option for some women wishing pregnancy.¹

RECOMMENDATIONS

- 3. UFE as a treatment for fibroids in patients wishing to preserve their fertility should be undertaken with full disclosure to the patient about the limitations of such a procedure and the lack of existing data regarding future fertility and pregnancy outcomes. (III-C)**
- 4. UFE is contraindicated in women who have evidence of current genitourinary infection and/or malignancy. (II-2-B)**
- 5. Women who choose UFE as an alternative to hysterectomy should be counselled regarding the risk of major complications of UFE where hysterectomy may be urgently required and potentially lifesaving. In view of this small but important risk, UFE is relatively contraindicated in women who are unwilling to have a hysterectomy under any circumstances. (III-C)**

CONSENT

As for any procedural consent, time should be allowed for due consideration by the patient. Following a complete evaluation by the gynaecologist, patients who wish to go ahead with UFE, should discuss this with the radiologist responsible and, again, take time for sufficient consideration before the procedure is undertaken. Full consent will include a disclosure of options and potential complications. An example of a suitable consent form is included as Appendix 1 and a typical patient information leaflet as Appendix 2. General practitioners and referring physicians must be kept aware of the details of this new procedure and of its risks. An example of one such information leaflet is provided as Appendix 3.

Every effort should be made to avoid fibroid embolization procedures in the presence of an early pregnancy. While embolization can be carried out at any stage of menstruation if the radiologist is confident that the patient has taken adequate contraceptive precautions, UFE should only be performed in the early to mid-follicular phase of the cycle if adequate contraception has not been used. Patients who present for the procedure later in the cycle should be offered a repeat appointment after menses and this should be documented in the hospital notes.

THE PROCEDURE AND PERIOPERATIVE OPTIMIZATION

Urinary tract infection, if present, should be eradicated. An intrauterine contraceptive device, if present, should be removed prior to the procedure.

Adequate pre-procedural imaging of the fibroids with MRI or US should be available and reviewed prior to the procedure.

The menstrual history should be carefully checked and a pregnancy test done to exclude pregnancy, if appropriate. Appropriate consent will have been obtained following the consultation process.

Interventional radiologists may perform the procedure on an inpatient or outpatient basis. Performing the procedure early in the day improves the opportunity for better control of post-procedural pain. Hospital protocols should be available and should include a protocol on peri-procedural sedation and pain relief. UFE should only be carried out in a specialized angiographic suite equipped with digital subtraction angiography. The equipment should be such that multi-angulation is possible, allowing oblique views to be achieved and radiation dosage to be minimized.²⁸ Equipment with pulsed fluoroscopic capability can be helpful in this respect. Prior to the procedure, intravenous access will be established, allowing intravenous sedation and analgesia to be given during the procedure. Patient-controlled analgesia may be instituted following the procedure. Appropriate monitoring is mandatory, including pulse oximetry.²⁹ The existing CAR standards for interventional radiology should apply.

The objective of UFE for fibroid disease is to sufficiently reduce flow in both uterine arteries with particulate emboli that will produce ischemic necrosis of the more susceptible uterine fibroids but have no permanent adverse effect on the otherwise normal uterus.

A standard percutaneous transfemoral approach (usually right-sided) is used to access both internal iliac arteries. Occasionally left-sided or bilateral puncture(s) may be used. Having confirmed the position of the catheter in the internal iliac artery, a guide wire is manipulated into the uterine artery and the catheter advanced over the wire. Contrast is injected to confirm satisfactory catheter position within the uterine artery. Arteriography is performed at this stage documenting the vascularity and size of the fibroid uterus as well as satisfactory positioning of the catheter. Embolization is then performed.

The most commonly used agent is polyvinyl alcohol, a well-established non-biodegradable agent available in a variety of sizes, although experience is being accumulated with newer agents. The embolic agent is mixed with contrast as it is injected in order to monitor particle location as well as the progress of embolization. Frequent test injections of contrast may also be used. As the particles obstruct the arterial tree, the speed of contrast clearance will decrease until it reaches a point of stasis or even reflux within the uterine artery. This may serve as an end-point for embolization. A more conservative procedure is used by some radiologists with the end point a *slow* rather than *absent* flow in the uterine artery. The efficacy and difference in complication rates between these 2 approaches require further assessment.

Adequate patient monitoring and pain control is essential in the post-procedural period. There are numerous published approaches to pain management, including narcotics orally or

by patient-controlled analgesia, anti-emetics, and, more recently, regional or epidural administration. Consultation between radiology, gynaecology, and possibly anesthesia in some centres may be required.

Once the patient has been determined to be a candidate for embolization, the procedural technique is in the hands of the radiologist. After the procedure, the patient is jointly in the care of radiologist and gynaecologist (and possibly the anesthesiologist). The single most important element in the continuing care of the patient is that the patient should have rapid access to a named qualified health provider who will be in a position to allay any anxieties relating to expected sequelae and also to act immediately if there is any question of the development of a serious problem.

Radiologists may take principal medical responsibility for the care of a patient for part or all of the hospital stay on the same basis as any other registered medical practitioner, provided that their skills, training, and available facilities are sufficient to ensure appropriate care until responsibility is reassumed by the referring medical practitioner. Where radiologists are working in a hospital without a gynaecological unit, agreed upon procedures for communication between clinicians to allow rapid recourse to the appropriate specialist are essential. As the gynaecologist, radiologist, and sometimes anesthetist and primary care provider are involved in the management of the patient, it is important that these individuals undertake a team approach to potential complications to ensure that the patient receives appropriate care when required.

RECOMMENDATIONS

6. **Genitourinary infection is the predominant cause of serious morbidity and mortality. Further research on the utility of prophylactic antibiotic therapy and the value of pretreatment screening for infection is needed. (II-2-B)**
7. **A gynaecologist who is familiar with UFE should evaluate all patients considered for UFE before the procedure is booked and a consensus on the suitability of the procedure achieved between the gynaecologist and radiologist. (III-C)**
8. **Only radiologists with specialized embolization experience and techniques should perform UFE. (III-C)**

SIDE EFFECTS AND COMPLICATIONS

Perioperative risks and complications include infection, bleeding, and hematomas at the groin femoral artery puncture site; allergic or anaphylactic reactions to the iodinated contrast dye; and incomplete uterine artery occlusion as well as misembolization of non-target organs.³⁰⁻³³ Such complications occur in approximately 1% to 2% of procedures. Puncture-site hematomas often occur but are unlikely to have significant consequence. Serious adverse reactions to the contrast medium are

rare and, in non-diabetic women with normal renal function, it is unusual for problems to arise with typical dosage of contrast. Spasm in the uterine artery, if excessive, can be minimized with an intra-arterial vasodilator or micro-catheter techniques, although arterial dissection or occlusion may prevent effective embolization of that artery.

A. EARLY OR ACUTE ABDOMINAL PELVIC PAIN

Virtually all women experience some degree of acute pain, often requiring hospitalization with intensive pain management protocols and monitoring. No correlation has been established between uterine size, myoma number or size, duration of procedure, quantity of polyvinyl alcohol particles used, or clinical outcome of the treatment.² The pain is thought to be due to non-specific ischemia of the uterus and fibroids, and responds to pain control including opiates and non-steroidal anti-inflammatory drugs (NSAIDS).²

B. POSTEMBOLIZATION SYNDROME

Up to 40% of women experience a constellation of signs and symptoms including diffuse abdominal pain, generalized malaise, anorexia, nausea, vomiting, low-grade fever, and leukocytosis.³² The syndrome is self-limiting and usually resolves within 48 hours with conservative and supportive therapy, consisting of intravenous fluids and adequate pain control, including NSAIDS.

C. INFECTION

The incidence of febrile morbidity and sepsis following embolization has been reported to be between 1.0% and 1.8%.³⁰⁻³³ The infections have included pyometria with endomyometritis, bilateral chronic salpingitis, tubo-ovarian abscess, and infected myomas. The most frequent pathogen isolated has been *Escherichia coli*.³³ Some women have responded to antibiotic therapy but others have required prolonged hospitalization, intensive therapy, and hysterectomy. One woman died following uterine artery embolization, despite an abdominal hysterectomy performed 17 days after embolization and intensive therapy. Prophylactic antibiotics have not been shown to be effective and their use should be reserved for women at higher risk of infection, according to established guidelines.³⁴

D. PERSISTENT OR CHRONIC PAIN

In 5% to 10% of women, the pain persists over 2 weeks. When it lasts longer than 2 to 3 months, persistent pain in the absence of infection does not resolve spontaneously, and it may require surgical intervention. Hysterectomy for post-embolization pain has been reported in up to 2% of women within 6 months of the embolization.^{31,32,35}

E. OVARIAN DYSFUNCTION

Transient and permanent symptoms indicative of ovarian failure have been reported by up to 10% of women after uterine

artery embolization. Underlying factors leading to ovarian dysfunction are unknown, but the evidence indicates that women over the age of 45 are more likely to experience post-embolization ovarian failure.^{30,36} Ovarian failure is of great consequence when preservation of fertility is desired.

F. MENSTRUAL DYSFUNCTION

Improvement in menstrual bleeding in up to 90% of women following uterine artery embolization has been reported.^{11,12} The menstrual improvement is age dependent, the highest being after age 50. Transient and permanent amenorrhea has been reported in 15% and 3% of women, respectively.^{16,31,37} Amenorrhea after embolotherapy is also highly age dependent and is reported to be related to waning ovarian function.

G. TRANSCERVICAL MYOMA EXPULSION

Following artery embolization, spontaneous expulsion of myomas through the cervix has been reported to occur in approximately 5% to 10% of women.^{32,38,39} Sixty percent of women with submucous myomas, confirmed by hysteroscopy, passed myomas vaginally, following uterine artery embolization.³⁹

H. UTERINE WALL INTEGRITY

The physical characteristics, integrity, and the histopathologic features of the uterine wall after uterine artery embolization remain unknown. Uterine wall defects,⁴⁰ uterine fistula,⁴¹ and 1 case of diffuse uterine necrosis⁴² following uterine artery embolization have been reported. Although normal pregnancies and deliveries following uterine artery occlusion have been reported, there is insufficient long-term data regarding reproductive outcome following this procedure and it would be prudent to reserve embolization for women who will not wish pregnancy.^{26,27,43}

I. HYSTERECTOMY

The number of women who proceed to hysterectomy following uterine artery embolization has been used as an indicator for the measurement of treatment failure.^{11,12} The rate of hysterectomy within 6 months of embolization has been reported to be 1% to 2%, and the indications have included infection, persistent bleeding, persistent pain, fibroid prolapse, and uterine malignancies.^{12,13,30,38}

K. MORTALITY

Please see the section "Advantages and Risks of UFE" earlier in these guidelines.

PROFESSIONAL RESPONSIBILITY

It is the responsibility of the gynaecologist referring a patient for UFE and of the radiologist to have adequate understanding of the procedure, and a willingness to work together to guarantee proper patient selection, appropriate follow-up, and treat-

ment of complications. The gynaecologist must be able to intervene with a surgical remedy should a complication necessitate this. The radiologist must have extensive experience with selective arterial embolization and thorough knowledge of the anatomy and risks of the procedure, and/or have formalized training on the techniques of UFE.

RECOMMENDATION

9. The particular responsibilities of both gynaecologist and radiologist should be established prior to treatment and be set out in a relevant hospital protocol. A particular physician must be responsible for the patient at all times. (III-C)

CENTRALIZED CANADIAN NATIONAL REGISTRY FOR UFE

The concept of a national registry has been increasingly employed as new procedures or treatment methods are introduced throughout the world. Examples are the European registry for aortic stent grafting, and the recent UFE and Legs for Life registries in the United States. The registry affords an opportunity to continuously monitor the frequency and success of the procedure, particularly as newer and older approaches are debated.

Data would be collected from gynaecologists, radiologists, and patients. Registry forms, patient information sheets, and consent forms would be sent out to radiologists and gynaecologists in a manner and using resources yet to be determined by a joint SOGC/CAR/CIRA committee.

A standardized SOGC/CAR/CIRA-approved patient information sheet could form the basis of informed consent. The patient's consent for telephone follow-up would also be obtained prior to the procedure. A series of simple forms should be sufficient to collect patient information and clinical and procedural data.

This data should become part of a national database. The aim of the registry should be to determine the periprocedural and late complication rates of UFE as well as the clinical outcomes and "treatment satisfaction." Every 12 months, the patient would be contacted directly and a further telephone questionnaire completed.

RECOMMENDATION

10. A Canadian national registry of numbers, indications, outcomes, complications, and successful pregnancies associated with UFE should be created and jointly administered and funded by the SOGC, CAR, and CIRA. (III-C)

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APPENDIX I

CONSENT FORM FOR UTERINE ARTERY (FIBROID) EMBOLIZATION

I have given the patient, _____, written information about fibroid embolization and have discussed this procedure and the alternatives with her. I have informed her of the possible complications and sequelae and given her time to think about other options and answered her questions. I am trained and qualified to carry out this procedure.

Signed: _____

Name (in capitals): _____
(Interventional Radiologist)

Date: _____

I have read and understood the explanation about fibroids and how they can be treated. After talking to my gynaecologist, _____, and interventional radiologist, _____, and having had time to think about the options, I have decided to undergo fibroid embolization (also known as uterine artery embolization or uterine fibroid embolization).

I consent to hysterectomy if I develop a serious complication that requires it. I recognize that fibroid embolization is a relatively new procedure and accept that the long-term benefit of this treatment has not yet been studied. I also understand that I must have regular checkups so that my gynaecologist and interventional radiologist can make sure that I am well and at the same time obtain more information about the results of the procedure. I also give my consent to my information being submitted in confidence to a national registry.

Signed: _____

Name (in capitals): _____
(Patient)

Date: _____

FIBROID EMBOLIZATION: INFORMATION FOR PATIENTS

This leaflet explains the options for treatment of fibroids and, in particular, describes a technique known as fibroid embolization.

WHAT ARE FIBROIDS?

Fibroids are common benign growths of the muscle wall of the uterus (also called the womb), which can cause several problems depending on their size and position. Some women with fibroids have heavy, prolonged, and/or painful periods. In other women, fibroids may be associated with problems in becoming pregnant. There are many other possible causes of heavy menstrual bleeding and there are other more common causes for fertility problems. Before considering treatment for fibroids, it is important to make sure that there are no other conditions causing the symptoms.

Sometimes fibroids press on the surrounding structures and cause difficulty in passing water or give a feeling of fullness. Fibroids sometimes occur as single growths, but frequently women have several fibroids within the uterus. They can vary in size, from being the size of a cherry to the size of a watermelon.

It is not known why fibroids develop but they are known to be dependent upon the estrogen hormone in the body. After menopause (change of life), when there is much less estrogen in the body, fibroids should stop growing or may shrink, although larger fibroids tend to persist.

The majority of fibroids do not require treatment. However, when fibroids result in pain or heavy bleeding, there are many alternatives available to improve these symptoms. Many women go through life having fibroids without being aware of it and having no gynaecological symptoms. However, if treatment is necessary, it will be important to consider the choices carefully.

TREATMENT OPTIONS FOR FIBROIDS

MEDICATION

Drugs will not cure fibroids but may relieve some of the symptoms. Talk to your doctor about the medications that may be helpful in your situation.

GnRH α

There is one type of hormone drug available that can temporarily reduce the size of fibroids: GnRH α . This drug fools the body into thinking that it is going through menopause, so the

fibroids shrink. However, as soon as the drug is stopped, the fibroids tend to grow back to their original size or sometimes larger than before within a short time. This drug can only be given for 6 months, as after that it can cause thinning of the bones. It is mainly used to reduce the size of the fibroids just before surgery to make the operation easier.

SURGERY

Two main types of surgery are performed to cure fibroids.

HYSTERECTOMY

Hysterectomy means removal of the uterus. This is the most effective treatment for fibroids as there is no possibility that the fibroids can regrow afterwards. Hysterectomy is a major operation and patients usually need to stay in hospital for a couple of days after surgery, depending on the type of operation and initial recovery. Rest afterwards is essential and in some cases up to 6 weeks of reduced activity will be recommended.

Following hysterectomy, women can no longer become pregnant. Hysterectomy is not suitable for people who have not completed their family, especially those seeking fertility treatment. If the ovaries are not removed, the hysterectomy will not cause hormonal changes.

MYOMECTOMY

Myomectomy is also a major operation as it involves cutting the fibroids out of the uterus but reconstructing the wall of the uterus to leave it in place. The advantage of this procedure is that, as the uterus is left behind, it is possible to become pregnant. There are 2 possible disadvantages. Firstly, this surgery can leave behind adhesions (scarring) inside the pelvis, which can, at worst, cause the fallopian tubes to become blocked. This would then prevent pregnancy from occurring. Secondly, as it is an abdominal operation and the fibroids carry much blood supply, there is a risk of complications including hemorrhage and organ injury, and the recovery time is similar to that of a hysterectomy.

FIBROID EMBOLIZATION

For many years, embolization (blockage of the arteries) of the

uterus has been performed for a variety of medical conditions. For the past 10 years, this technique has been used for patients with symptomatic fibroids. A group in Paris first reported it in 1995. This procedure does not require a general anesthetic or a major incision. This treatment is called *uterine fibroid embolization (UFE)*.

INFORMATION FOR PATIENTS UNDERGOING FIBROID EMBOLIZATION

WHAT IS FIBROID EMBOLIZATION?

Fibroid embolization is a new way of treating fibroids by blocking off the arteries that feed them, the uterine arteries, and making the fibroids shrink. It is performed by a radiologist, rather than a surgeon, and is an alternative to an operation. Fibroid embolization was first performed in 1995 and, since then, many thousands of women have undergone the procedure worldwide.

WHY WOULD I CHOOSE FIBROID EMBOLIZATION?

Other tests that you have had done show that you have fibroids and that these are likely the cause of your symptoms. Your gynaecologist and your family doctor will have told you all about the problems with fibroids and discussed with you ways of dealing with them. Hysterectomy, myomectomy, and embolization are possible treatments. Your doctor can address with you the risks and advantages of each so that you can make a decision regarding the most appropriate choice for your personal situation.

WHO WILL DO THE FIBROID EMBOLIZATION?

A specially trained doctor called an interventional radiologist will do the fibroid embolization. Radiologists have special expertise in using X-ray equipment and also in interpreting the images produced. They look at these images during the procedure. Interventional radiologists are trained to insert needles and fine catheters into blood vessels and through the skin in order to perform certain minimally invasive treatments.

WHERE WILL THE PROCEDURE TAKE PLACE?

Generally fibroid embolization takes place in the X-ray department, in a special "procedures room" adapted for such a procedure.

HOW DO I PREPARE FOR FIBROID EMBOLIZATION?

You will probably be asked not to eat for 4 hours beforehand, although you may be told that it is all right to drink some water. You may receive a sedative to relieve anxiety. You will be asked to put on a hospital gown. As the procedure is generally carried out using the big artery in the groin, you may be asked to shave the skin around this area. If you have any allergies, you must let your doctor know. If you have previously reacted to intravenous

contrast medium, the dye used for kidney X-rays and CT scanning, then you must also tell your doctor about this.

WHAT ACTUALLY HAPPENS DURING FIBROID EMBOLIZATION?

You will lie on the X-ray table, generally flat on your back. You need to have a needle put into a vein in your arm, so that the radiologist can give you a sedative or painkillers. Once in place, this will not cause any pain. You may also have a monitoring device attached to your chest and finger and may be given oxygen through small tubes in your nose.

The radiologist will keep everything sterile and will wear a surgical gown and operating gloves. The skin near the point of insertion, probably the groin, will be swabbed with antiseptic and then most of the rest of your body covered with surgical blankets and towels. The skin and deeper tissues over the artery in the groin will be anaesthetised with local anaesthetic, then a needle will be inserted into this artery. Once the radiologist is satisfied that this is correctly positioned, a guide wire is placed through the needle and into this artery. Then the needle is withdrawn allowing a fine, plastic tube, called a catheter, to be placed over the wire and into this artery. The radiologist will use the X-ray equipment to make sure that the catheter and the wire are then moved into the correct position, into the other arteries that feed the fibroid. These arteries are called the right and left uterine arteries. A special X-ray dye, called contrast medium, is injected down the catheter into these uterine arteries and this may give you a hot feeling in the pelvis.

Once the fibroid blood supply has been identified, fluid containing thousands of tiny particles is injected through the catheter into these small arteries, which nourish the fibroid. This blocks up these small blood vessels so that the fibroid is starved of its blood supply. Both the right and the left uterine arteries need to be blocked in this way. It can often all be done from the right groin but sometimes it may be difficult to block the branches of the right uterine artery from the right groin and so a needle and catheter may need to be inserted into the left groin as well.

At the end of the procedure, the catheter is withdrawn and pressure is firmly applied on the skin entry point for approximately 10 minutes, to prevent any bleeding.

WILL THE PROCEDURE HURT?

When the local anaesthetic is injected, it will sting to start with, but this soon eases off and the skin and deeper tissues should then feel numb. The procedure itself may become painful. However, there will be a nurse, or another member of staff, available to administer painkilling medications through the IV in your arm if needed.

As the dye, or contrast medium, passes around your body, you may get a warm feeling, which some people can find a little unpleasant. However, this soon eases off and should not concern you.

HOW LONG WILL IT TAKE?

Every woman's situation is different and it is not always easy to predict how complex or how straightforward the procedure will be. The procedure typically takes an hour, but depending on your anatomy, it may take 30 to 120 minutes.

WHAT HAPPENS AFTERWARDS?

You will be taken back to a recovery room or to your ward on a stretcher. Nurses will carry out routine observations, such as taking your pulse and blood pressure, to make sure that there are no untoward effects. They will also look at the skin entry point to make sure there is no bleeding from it. You will generally stay in bed for 6 hours. Most patients experience pain such that they need narcotics either by pill or intravenous for several hours following the procedure. You may be kept in hospital over night.

The day after the procedure, you may resume normal activities as your symptoms allow, but most women require some time off work as they continue resting and taking pain medication for the first few days. Some patients may feel very tired for up to 2 weeks following the procedure, although some people feel fit enough to return to work 3 days later. However, patients are advised to take at least 2 weeks off work following embolization.

ARE THERE ANY RISKS OR COMPLICATIONS?

Fibroid embolization is normally a safe procedure but there are some risks and complications that can arise, as with any medical treatment. There may occasionally be a small bruise, called a hematoma, around the site where the needle has been inserted, and this is quite normal. If this becomes a large bruise, then you should contact your radiologist to ensure that no treatment is needed. Most patients feel some pain afterwards. This ranges from very mild pain to severe cramping, period-like pain. It is generally worst in the first 12 hours but will probably still be present when you go home. While you are in hospital, this can be controlled by powerful painkillers. If the pain is associated with nausea or vomiting, anti-nausea drugs will be prescribed. You will be prescribed further medications to take at home.

Most patients get a slight fever after the procedure, which may be due to degeneration of the fibroid. The painkillers you will be given will help control this fever. A few patients get a vaginal discharge afterwards, which may be bloody. This is usually due to the fibroid breaking down. Usually, the discharge persists for approximately 2 weeks from when it starts, although occasionally it can persist intermittently for several months. This is not in itself a medical problem. If necessary, wear sanitary pads rather than tampons.

If the discharge becomes purulent (has pus in it) and if you also have a high fever and feel unwell, infection may be present and *you should ask to see your gynaecologist immediately. Infection is the most serious complication of fibroid embolization.* This happens to perhaps 2 in every 100 women having the procedure. The signs that the uterus is infected after embolization include pain, pelvic tenderness, and a high temperature. Lesser degrees of infection can be treated with antibiotics. Once severe infection has developed, it is generally necessary to have an operation to remove the uterus—a hysterectomy. One patient has died after fibroid embolization because of severe infection. *If you would not want a hysterectomy under any circumstances, then it is probably best not to have fibroid embolization performed.*

Up to 15% of women spontaneously expel a fibroid, or part of one, usually 6 weeks to 3 months afterwards. If this happens, you are likely to feel period-like pain and have some bleeding.

A few women have undergone an early menopause after this procedure. This has probably happened because the blood supply to the ovaries has been affected. Early menopause is more common in women who are over the age of 40 when they have UFE.

WHAT ARE THE RESULTS OF FIBROID EMBOLIZATION?

The results from most scientific series are very positive, with symptom relief in 50 to 90% of patients. Patients with fibroids and heavy bleeding as their reason for UFE typically have the best results. On average, shrinkage of fibroids is about 50% of the volume of each fibroid. The majority of women are pleased with the results. If having a baby in the future is very important to you, you need to discuss this with your doctor, as there are reports that there may be more complications in pregnancy following UFE. For women who are interested in future fertility, a myomectomy may be a better choice.

This leaflet should answer some of your questions about fibroid embolization. However, this is only a starting point for discussion about your treatment with your doctors.

Make sure you receive enough information about the procedure before you sign the consent form.

Fibroid embolization is considered a safe procedure, designed to improve your medical condition and save you having a major operation. There are some risks and complications involved and, because there is the possibility of a hysterectomy being necessary to deal with complications, make sure that you have discussed all the options available with your doctors.

APPENDIX 3

UTERINE ARTERY EMBOLIZATION (UFE) FOR THE TREATMENT OF SYMPTOMATIC UTERINE FIBROIDS: POST-PROCEDURE INFORMATION FOR GENERAL PRACTITIONERS

Your patient _____ of _____ was referred to _____ (interventional radiologist) for UFE by _____ (gynaecologist). The procedure was carried out successfully and without immediate complication on _____ (date).

She was observed for _____ and discharged on _____.

Low-grade fever and period-like pain can persist for up to 2 weeks and she has been supplied with analgesics to help this. Vaginal discharge can also occur and is usually of no clinical consequence, although she has been told to wear sanitary pads rather than use tampons if this happens.

A purulent discharge warrants an urgent referral back to the gynaecologist and, if accompanied by excessive pelvic pain and tenderness with high fever, emergency referral is advised.

The patient is aware of the signs of infection and its consequences. She is in possession of a post-procedural information sheet (copy enclosed) that can be used if a family doctor other than you is on duty. We plan to see the patient again in one month.